

American Society of Health-System Pharmacists
Comments to FDA's Drug Safety and Risk Management
Advisory Committee about Ways to Improve the
Usefulness of Consumer Medication Information (CMI)

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The American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to provide comments to FDA's Drug Safety and Risk Management Advisory Committee on the usefulness of consumer medication information (CMI). My presentation has not been paid for by any organization or pharmaceutical company. ASHP receives monies from external organizations through their purchase of advertising in our journal, leasing of exhibit space at our annual conventions, and through corporate sponsorship (fully disclosed to participants) for Continuing Education and related publications.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. ASHP has a long history of medication-error prevention efforts, and we believe that the mission of pharmacists is to help people make the best use of medicines. Assisting pharmacists in fulfilling this mission is ASHP's primary objective. The Society has extensive publishing and educational programs designed to help members improve their professional practice, and it is the national accrediting organization for pharmacy residency and pharmacy technician training programs. ASHP believes that private-sector publishers, including professional associations, must play an important role in the creation and dissemination of useful medication information.

ASHP applauds the progress made by community pharmacies in *voluntarily* providing written medication information on prescription drugs to consumers. Findings from the December 21, 2001, report to DHHS and the FDA show that substantial progress has been made in the proportion of prescriptions that are accompanied voluntarily by written medication information when dispensed in community pharmacies. In this report, almost 90% of prescriptions were accompanied by such information. By comparison, in 1994 the FDA and National Association of Boards of Pharmacy (NABP) surveys found that only 55-64% of consumers reported receiving written medication information. While the almost 90% current rate for providing written medication information greatly exceeds in terms of absolute percentage the 75% goal established for 2000 in Public Law 104-180, and the distributed information achieved scores exceeding 90% for several key measures of usefulness (e.g., scientific accuracy,

currency, and non-promotional tone), continued attention to improving the usefulness of this information remains important as reflected in widely variable scoring of the information quality, particularly regarding the risks of treatment. However, as acknowledged in DHHS' 1996 Action Plan, it is expected that as the Plan is implemented additional information will be gained regarding what constitutes "useful," and that any associated guidelines should be subject to periodic review, evaluation, and refinement. Therefore, ASHP believes that the current study should be viewed principally as a further refinement of the definition of "useful" rather than as an indictment of the current voluntary efforts. In fact, careful inspection of the criteria used in the current report indicates that "usefulness" was defined in many cases by criteria that were not specifically enumerated in the 1996 Action Plan.

For example, the 1996 Action Plan criteria for useful prescription medicine information does not specify the inclusion of pharmacologic-therapeutic class information as a component of what is considered sufficiently specific and comprehensive, yet this weighs heavily in the current report findings where 3 out of 8 subcriteria used to measure this component in the glyburide information are about the provision of pharmacologic-therapeutic information. Furthermore, the consumer relevance of describing atorvastatin as an HMG-CoA reductase inhibitor is questionable, particularly since many health professionals have difficulty with this cumbersome class designation and therefore have resorted to the more common "statin" descriptor.

The source and/or rationale for some criteria also are unclear yet weigh importantly in poor adherence determinations. Examples include a criterion about kidney disease for atorvastatin and the 8-hour, missed-dose window specified for atenolol, atorvastatin, and glyburide. Likewise, the equal weight given to the subcriterion that patients should ask the prescriber or pharmacist about any questions or concerns and the one about the availability of a longer professional leaflet is skewed relative to the components identified in the Action Plan. In the spirit of the Action Plan regarding the evolving nature of the definition of "usefulness," what seems most important is that criteria that will be used in judging the usefulness of written consumer medication information should be widely agreed upon and circulated to both public and private publishers so that they will be fully aware of the yardsticks against which their information will be measured. In doing so, however, it is important that FDA not lose sight of the goal of the 1996 Action Plan that some flexibility in content be allowed.

Missing from the current report are recommendations on how to further improve the usefulness of prescription medication information. Therefore, ASHP recommends that FDA solicit advice in the form of an advisory panel of experts and public- and private-sector stakeholders regarding further refinement of the definition of "usefulness" and the associated specific criteria that will be used in evaluating adherence to this definition. This panel also should recommend mechanisms for ensuring that publishers and providers of consumer medication information are fully advised about such ongoing developments so that appropriate changes can be implemented. Likewise, attention should be given to possible implementation of other recommendations (e.g., implementation activities) included in the 1996 Action Plan. As part of this strategy, the advisory panel should be charged with identifying priority areas and interventions for improving the usefulness of consumer medication information. In addition, this panel should provide advice on possible interventions in the development and distribution of consumer medication information aimed at improving information quality. The role and

importance of outcomes research in the context of measuring the usefulness of consumer medication information also should be addressed by this advisory panel.

ASHP strongly believes that the proper course for the FDA is to defer regulatory action for now, while pharmacists, pharmacy facilities, and private-sector medication information publishers and providers maintain their commitment to improve the usefulness of information that is provided to 95% of patients by 2006. As part of ASHP's commitment to the mission of pharmacists for helping patients make the best use of their medications, the Society will continue to follow the findings of, and make recommendations to, FDA and other groups as well as make appropriate enhancements to its patient medication information aimed at improving usefulness. In addition, ASHP remains ready to assist the FDA in further implementing the recommendations of the 1996 Action Plan, both as a professional pharmacy association and publisher, and in serving in any formal advisory capacity that the agency pursues in this regard.

ASHP Accomplishments Relating to Patient Medication Information

ASHP has long been an advocate of the role of pharmacists in providing useful written and oral counseling patients about their medications. ASHP's advocacy extends back to recommendations provided to Congress and FDA on proposed drug safety amendments to the Food, Drug, & Cosmetic Act regarding patient package inserts (PPIs) in the mid 1970s, where the Society voiced its support of written patient information on prescription medications as part of a comprehensive system providing patients with meaningful information about drug therapy. In addition, ASHP was a cosponsor of the Joint Symposium on Drug Information for Patients in November 1976, which for the first time gathered the collective wisdom of pharmacy, medicine, nursing, consumer organizations, the pharmaceutical industry, and the federal government on PPIs.

ASHP has a 25-year history of publishing medication information intended for educating patients about their drug therapy. In 1975, ASHP's Board of Directors approved the Society's "Guidelines on Pharmacist-Conducted Patient Counseling," which recognized the responsibility of pharmacists and other health professionals to properly inform patients about their drug therapy and identified the key elements to be addressed in such counseling; these guidelines have been expanded greatly over the years and were last revised in 1997. With release in 1978 of the first edition of the "Medication Teaching Manual: A Guide for Patient Counseling," ASHP became one of the first private-sector organizations to publish medication monographs intended for educating patients. This Manual was developed by the Medication Teaching Advisory Committee, which ASHP formed in cooperation with the American Hospital Association (AHA) and US Department of Health, Education, and Welfare's (now DHHS) Bureau of Health Education. While this initial effort originally was intended to define needs and set priorities in helping *hospital* staff teach patients about the rational use of medications, ASHP's efforts over the years have extended to patient-education programs conducted by health-care professionals in a variety of settings, including community pharmacies, and directly to consumers through resources like ASHP's safemedication.com website and the National Library of Medicine's MedlinePlus website, which both include patient medication information developed by ASHP.

ASHP is a member of the National Council on Patient Information and Education (NCPPIE) and was a member of the DHHS Steering Committee for the Collaborative Development of a Long-range Action Plan for the Provision of Useful Prescription Medicine Information (facilitated by the Keystone Center), which submitted its plan to the Secretary of HHS in December 1996, and is the basis for criteria used in determining the usefulness of written prescription information provided in community pharmacies. ASHP is a past recipient of an award of excellence for consumer education materials from the FDA and the National Coalition for Consumer Education (NCCE) and was one of the first private-sector publishers to incorporate the guidelines of DHHS' 1996 Action Plan for criteria, goals, layout, and language on useful prescription medication information in its patient resources. These guidelines were addressed initially in 1997-1998 as part of a significant reformatting of ASHP's Medication Teaching Manual and associated electronic resources (e.g., MedTeach software, MedMaster database, safemedication.com website).